“One door, one key principle”, does it really exist?

Master Thesis

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Abstract

The popularity of GMO products around the world increased in the last decade. Nowadays, GMOs are used not only for industrial purposes, but also in the food sector. Based on safety reasons, each GMO has to be scientifically evaluated before entering the market, either as imported food or feed products or as a product for cultivation. The legal base for the authorization of the GMO products in the European Union is Regulation (EC) No. 1829/2003, which is seen as "one door, one key" principle in the authorization process. This paper analyses the current situation within the European Union in relation to GMO authorisation procedure. First, the history of GMO legislation is explained, and then the compliance requirements under the current regulatory framework are evaluated. Secondly, relevant stakeholders were interviewed in regards to the legislation, such as companies, the European Commission and a researcher. The data collected from the interviews was analysed. Finally, analyses for forthcoming changes in the legislation are made, based on the research. The research paper shows that the authorisation for cultivation is much less preferred and the use of the principle as such is limited. Consequently, the preference from the biotech companies for such a grant is limited and the authorization- not granted from the European Commission.

Key words: European Commission, Genetically Modified Organisms, GMO Authorisation

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List of Abbreviations

BSE	Bovine Spongiform Encephalopathy
DG SANCO	Directorate General for Health and Consumers
EA	Environmental Assessment
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
GM	Genetically Modified
GMO	Genetically Modified Organism
MS	Member State
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organization
WTO	World Trade Organization

Content

1. Introduction

During the last few decades Agriculture and especially the Food sector has become more important and has taken leading positions in the European Union's agenda and in national strategies for development in the Member States. According to the European Commission, on one hand food safety policy has to ensure safe and healthy food for the consumers as well as protection of their right for food and on the other hand allow smooth trade and free movement of foods (European Commission, 2013). This balancing act forms a particular challenge for foods such as GMOs, whose potential impact of health are not yet known.

During the last decades European Food Law has gone through steps of improvement and developed harmonisation measures, which aimed inter alia at securing the free movement of foodstuff as well as securing their safeness.

The level of harmonisation chosen has always played a key role in establishing the internal market for foods. The major switch has been triggered by the introduction of the White paper on Food Safety (European Commission, 2000), where the “from farm to the table” principle introduced a total harmonisation approach to food law.

Nowadays the role of GM foods is taking leading position in the feed sector, not only in the EU, but also all over the world. This trend is moving towards the food sector as well. Therefore, GMOs have been among the first products in foods that were subject to this new harmonisation method in EU food law. The first GMO specific legislation in the European Union was Directive 2001/18/EC on deliberate release into the environment, which was later amended by Regulation (EC) No. 1829/2003 on authorisation of genetically modified food and feed and cultivation purposes at the same time. Before the introduction of these specific legislations, there were sector specific regulations, which are going to be discussed in the next chapter.

If the GMO is to be used in food or feed without cultivation - a single application for both food and feed purposes is enough (Regulation 1829/2003).If the GMO is to be used in food or feed with cultivation in the EU - companies submit an application for both cultivation and food/feed purposes under the same Regulation. If the GMO is not to be used in food or feed - applying for authorisation for cultivation is enough (Directive 2001/18).

According to the definition of the Directive 2001/18/EC, “genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;” (European Commission, 2001).

Thus, according to the current law, “the one door one key principle” can be applied for the GMO approval procedure. It is an authorisation process for both types of authorisations (for food/feed and for cultivation), carried out via one risk assessment and can be filed under one common application.

The major step of the authorisation procedure is the risk assessment part done by EFSA, as it can be seen in the figure below. The risk assessment is part of the procedure for both types of authorisation. If the risk assessment results in negative opinion about the GMO product, it cannot be released into the environment, be present in food or allowed for import. In case of a positive opinion, it is subject to the European Commission's decision if the authorisation will be granted or not.

The general overview of the approval procedure for GMO's can be found in Figure 1, below.

Figure 1 Approval procedure for Authorisation of GMOs in European Union according to Regulation (EC) No. 1829/2003[1]

The procedure can be divided into 4 major steps as:

1) Filing an application by the BO with all the accompanying information about the GMO;
2) Evaluation of the application by EFSA, where risk assessment procedure is included;
3) Report by the EFSA, which is forwarded to the EC for the decision;
4) Decision for the authorisation of the GMO;

This procedure is valid for both of the authorisations.

[1]Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, where in Article 7 of the legislation the Authorisation procedure is explained.
Available on the internet at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003R1829:20080410:EN:PDF
(last accessed 29/09/14)

1.1. Statement of the problem

The hypothesis of this research is that despite all efforts, the one door one key principle in practice does not lead to one authorisation of the GMO for both cultivation and food and feed uses. If so, the “one door one key” principle in the EU does not work. There will be a closer look into possible reasons for this division between the legal principle and its application in practice.

There are two aspects of the “one door one key” principle in the EU in terms of GMO regulation. First, via this principle, EU tries to implement only one application procedure for both GMO release into the environment and GM food. Consequently, the idea is to have only one risk assessment. As far as it can be seen from the results of the Commission, only 2 GM crops are allowed for cultivation as of December 13, 2013. The difference in the numbers of GM crops authorised for food and feed uses and those for cultivation, shows that the principle doesn’t work smoothly and there is burden for the applicants for receiving an authorisation for GM cultivation.

Another aspect of this principle is the mutual recognition, which is not going to be analysed in this paper. The problem with it is that although GMOs are approved in the EU for cultivation, they are not allowed to be grown in all of the Member States, because of the Safeguard measures which some Member States enforce. According to the current law, they are allowed to implement the safeguard measure as of Art.24 of Regulation 1829/2003 and limit the cultivation of already authorised GMO products.

In this thesis there will be a closer look at the approval procedures, more specifically to the environmental and food approval procedures. Furthermore, it will be determined why so few products are authorised for cultivation compared to the authorisation of GM foods at EU level. In the discussion part, the analyses based on the interviews with different parties will be analysed, also why different Member States have decided to ban GMOs and what this is based on.

Subsequently, possible reasons behind the overall problem will be drawn.
Finally, the consequences of this limitation of the cultivation of GMO crops for Member States, consumers and trade will be discussed.

1.2. Research questions

This study aims to answer the following questions:

Main question:

Is the “one door one key principle” applied in practice?
If not, why is the principle not applied?

Sub-questions:

- How has GMO Food Law developed during the last years in terms of Food Safety?
- What is the current approval procedure to release GMO into the environment and for GM food?
- How do the procedures relate to each other?
- What is the result of the current approval procedure?
- What are the reasons behind it?
- What are the consequences?

1.3. Methodology

This study will be carried out using various primary and secondary legal sources, policy documents, scientific documents and interviews with companies experienced in the GMO approval procedure in the EU.

This thesis will show if the “one door one key” principle is applied in the day-to-day work of EU regulators. Later, the reasons will be developed in order to explain the difference between the law in the books and law in action. That will be done as desk research.

The first section starts with empirical research, where I will first map the genesis of the “one door one key” principle. In this respect, I will highlight the origins of the approval procedure, their development according to the “one door one key principle” and map their function and procedure.

Subsequently, the empirical research will continue and in the second part I will show that in action only a minority of GMO products have been approved accordingly to the principle as most products are not authorised for cultivation.

Next, I will identify several reasons for this difference and map their consequences.
In the end I will conclude with normative guidelines that need to be met in order to enforce the “one door one key principle”.

2. Background information

2.1 Development of the European Food Law

As a starting point for the European Union Food Law development, the Cassis de Djion Case[2] in 1979 can be discussed (ECC. Europa, 1979), where the Court of Justice of the European Union decided not in favour of Germany and from then on started a new phase of development for the Food Law (Meulen & Velde, 2011). As a consequence, Food Law became market oriented with vertical directives[3]. The case itself made major changes with introducing system of mandatory requirements and natural development of the harmonisation process. Another approach of the changes after the case is the doctrine of mutual recognition, which means that products which are marketed already in one of the Member States can be lawfully market also in other Member State.

In the early 1990's, after a huge food scandal, known as BSE crises, the need of GMOs regulation appeared in EU. EU council adopted the first measure controlling the GMO in the environment with Directive 90/220/EEC. (Winickoff, 2005).

The initial point of the introduction of the development of the General Food Law was the BSE[4] crises, which was the relation between BSE, Creutzfeld Jacob Disease and Food Safety (Neyer, 2000). It took very long time until the link between BSE and Creutzfeld Jacob Disease concerning humans was found. As soon as the authorities discovered it, a ban on UK beef was declared (Vos, 2000).According to the paper of Ellen Vos (Vos, 2000), the decision for the ban came too late. The peak of the BSE crisis was in early 90s and the response from the Committee came in 1996. During the crises 185,000 BSE cases were confirmed (EFSA, 2012). This gap of misinformation of the years between 1990 and 1996

[2] The applicant intended to import a liqueur, "Cassis de Dijon", into Germany from France. The German authorities refused to allow the importation because the French drink was not of sufficient alcoholic strength to be marketed in Germany: under the German law such liqueurs had to have an alcohol content of 25%, whereas the French drink only had an alcohol content of between 15 and 20%. The applicant argued that the German rule was a measure equivalent to quantitative restriction since it prevented the French version of the drink from being lawfully marketed in Germany.
The ECJ stated that the limitation of the free movement of goods could only be permitted in exceptional cases, for example in order to protect the health of the public, to protect the consumers or if a general public interest existed. However, these conditions in regard to the alcohol content for liqueurs were not met, which is why the product had to be allowed into Germany without hindrance.

[3]Meulen van der, B. 2013, 'The Structure of European Food Law', Laws 2013, 2, 69–98; doi:10.3390/laws2020069, pp. 74.what do you think of this reference?, it gives a quick explanation of what vertical directives means.

[4] Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, is a fatal neurodegenerative disease (encephalopathy) in cattle that causes a spongy degeneration in the brain and spinal cord. BSE has a long incubation period, about 30 months to 8 years, usually affecting adult cattle at a peak age onset of four to five years, all breeds being equally susceptible. In the United Kingdom, the country worst affected, more than 180,000 cattle have been infected and 4.4 million slaughtered during the eradication program.
The disease may be most easily transmitted to human beings by eating food contaminated with the brain, spinal cord or digestive tract of infected carcasses.

caused enormous consequences in economical aspect and completely changed food law regulation and radical changes were needed. At that time, the Committee structure was very different from the current one and it was as follows:
-Scientific Committee on Foodstuffs (SCF), represented by independent scientific experts in the field. The function of this committee is to give independent scientific advice.
-Standing Committee on Foodstuffs (StCF), consists of national representatives. The function of this committee is ensuring the political approval of the Member States involved.
-Advisory Committee on Foodstuffs (ACF), represented interest groups. The function of this Committee is to point out the interests of the groups involved (Vos, EU Food Safety Regulation in the, 2000).

In 1996 a Temporary Committee was formed to investigate the actions taken by the European Parliament during the crisis. The findings were quite negative for the image of the Commission and British Government. The statements have been mainly about misinformation, miscommunication, lack of transparency and "British thinking" involved in decision making, due to the high number of British representatives in the Committees[5]. That appeared to prove that the industry interests had been put ahead of consumer safety. All these facts had been accompanied by little coordination and cooperation between different DGs and risk regulation was shifted (Meulen & Velde, 2011).

Obviously, this report and the all the uncertainties in food law in Europe made the European Commission start thinking on this issue and take actions towards development of the General Food law.

A new approach in food safety was then introduced, where the priority was greater transparency in regulations and reinforcement and building mutual recognition principal and minimum harmonization standards (Alemanno, 2006). European food law had been more focused on trade than food safety issues. Mismanagement of the BSE crises led to the decision of the establishment of an independent food safety authority to carry out risk assessment and prevent such crisis from reoccurring (Alemanno, 2006). The BSE crises led to the second phase of the European Food Law development characterised by horizontal directives and stronger market orientation (Meulen & Velde, 2011).

The reaction of the Commission in terms of new development for a change came shortly after. In May 1997, the Green Paper was published (Meulen & Velde, 2011). The paper focused on general principles of food law as well as the high level of public health protection and safety of consumers, which lacked in the past. In terms of foodstuffs, the paper concentrated on free movement within the internal market. Furthermore, rationalisation of Community foodstuffs legislation was the priority in terms of enforcement (Meulen & Velde, 2011).

On the 2nd October 1997, the Amsterdam treaty[6] was signed. Objectives of this treaty agreed for improvements in public health and consumer protection as EU integration (Alemanno,

[5] The Scientific Veterinary Committee advising the European Commission was chaired by a British scientist, the Committee was under a significant pressure from the British Ministry of Agriculture, Fishery and Foods (MAFF).
[6] Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, as signed in Amsterdam on 2 October 1997.
Available on the internet at: http://www.europarl.europa.eu/topics/treaty/pdf/amst-en.pdf, (last accessed on 23/09/2013)

2006). Consequently, European food law was quite improved after the BSE crises in the field of risk analyses and risk management made a big step towards an integrated approach.

The response from the European Commission came on the 12th January 2000 with publishing the White paper on Food Safety (European Commission, 2000). In this paper, 80 actions for establishing and developing better food safety policies are described. The latter covers the safety over the whole food chain, so called from farm to table policy. Traceability is also one of the key issues discussed in the paper and all the decisions have to be scientific based. If it is necessary, for the safety of the consumers, precautionary principle and safeguard measures can be applied. Food safety controls have to be done more frequently to ensure a coherent, effective, dynamic food policy. All these measures are planned to achieve greater transparency and the highest possible consumer protection and consequently maintain the confidence in European food Authorities.

2.2 History of GM Food Regulation

In the next pages the history of the GM law will be explained. It will start with the introduction of the GM law towards the latest legislation for GMO authorisation in the European Union. The major steps in the legislations will be clarified, as well as the role of EFSA in the authorisation process.

2.2.1 Directive 90/219/EEC

In the last decades biotechnology has developed significantly. Consequently the law had to adapt and meet the needs to regulate the new food market including biotechnology. The first attempt for it was the Directive 90/219/EEC[7] of 23 April 1990 on the contained use of genetically modified micro-organisms for research and industrial purposes and 90/220/EEC[8] on deliberate release into the environment of genetically modified organisms (European Commission, 2000). At that times GMOs were still not considered for food purposes for humans, therefore the scope of the Directive was very limited. Consequently, the directive concerned GMOs only for experimental purposes and deliberate release for placing the product itself on the market, but didn't concern other products derived from the initial GMO products (European Commission, 2000).

The highlight of this directive is the risk assessment procedure prior to authorisation. Before releasing the GMOs into the environment each Member State had to carry out risk assessment, based on different criteria. GMO introduction into the environment is premised on the "step by step" principle whereby GMO containment is reduced, and the release scale is gradually increased, but only if earlier human health and environmental evaluations of previous steps indicate the next step can be taken. The directive still had to improve a lot in the area of definitions and risk assessment uncertainty. More specifically, there was lack of

[7] Available on the internet at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0219:EN:HTML (last accessed on 29/09/14)

[8] Available on the internet at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1990:117:0015:0027:EN:PDF (last accessed on 29/09/14)

common definition of the objectives and the methodology of risk assessment procedure (European Commission, 1996).

In the next paragraph the main elements of the GMO approval procedure on deliberate release into the environment of GMOs are explained. The first step that applicants should follow is to file notification to the "competent authority" of the Member State where the product will be placed on the market for the first time. The notification dossier should consist of risk analyses carried out and comply with requirements of the European Community for GMO products under Directive 90/220/EEC, more specifically Article 5 (2) (European Commission, 1990)

According to Article 6 of the Directive, upon receipt of the notification, the competent authority examines the dossier if it complies with this Directive; evaluates the risk posed by the release; records the conclusion. In paragraph 2, from the latest article, it is explained the competent authority has 90 days to make a decision.

If the opinion is favourable, the dossier should be forwarded to the Commission, if not, the applicant should be informed that the proposed release doesn't fulfil the requirements according to the directive (European Commission, 1990).

The next step of the procedure is that the Commission should forward the dossier to all the Member States. They have 60 days to raise objections, if not, the competent authority should grant the approval and issue a written consent (European Commission, 1990).

With the years, GMOs have started shifting from feed to food industry and considering the fact that GMOs are living organisms, by 1998 public concerns about the risk of GM crops on human health and the environment were increasing. Consequently, that led to the demand for consumer choice and more information on GM products. The Member States started expressing their concerns and doubts about the uncertainty of GM crops in respect to whether it is safe food for consumption. Parallel with that they started asking for changes (Winickoff, 2005).

During a meeting of the EU Council on Environment Ministers in June 1999, countries such as France, Denmark, Greece, Italy and Luxemburg, built their argument on Article 16 of Directive 90/220/EEC and pointed out their concerns about GMOs, it was consequently decided to block new authorisations until the Directive 90/220/EEC was not revised and significant changes were made. More specifically they wanted clear labelling and traceability system for GM foods. In that way, consumers could follow their food and preferences effortlessly when choosing between GMOs and other types of food. (Fernando-Macvean, 2013). The result came as de facto European moratorium[9]. After this decision by the Member States, authorisation process of GMOs was terminated. The authorisation process resumed when the new regulation came into force in 2004 (Winickoff, 2005).

[9] France and Greece - backed by Belgium, Denmark and Luxembourg - lead calls for de facto moratorium on new GMO approval at meeting of EU environment ministers and are later joined by Belgium and Austria, forming a minority of EU states that can block any vote on a new approval. During the moratorium, the EU refused the experimental or commercial growth of new gene crops or imports of new GMO-based food products. In or before 1998, approval was given for 18 biotech plants, including maize, rapeseed, chicory and soybeans.

2.2.2 Regulation (EC) 258/97

A significant moment in GMO history was in 1997, when Regulation (EC) 258/97 on Novel foods and Novel Food Ingredients was adopted (Europa E. , http://eur-lex.europa.eu, 1997). It was single regulation for both genetically modified foods[10] and novel foods[11] until 2003, when the regulation was amended.

The new Regulation (EC)258/97 governs genetically modified foods and new foods, which didn't exist up to that moment on the European market or derived from ingredients that haven't been used for human consumption within European Community (MOSELEY, 2002). The scope of the regulation includes the irradiated foods as well.

If the applicant has evidence that the food he is applying for approval, has been used within the EU before 15 May 1997, the food can be placed on the market and not assessed as novel food. But, if it cannot be proved that the product existed on the market before the date of 15 May 1997, the food is seen as novel and further risk assessment has to be done according to the regulation (Hermann, 2009).

Regulation (EC) 258/97 became the extension of the Directive 90/220/EEC and was based on it, so both legislations were incorporated and enforced together.
The principle of Reg. (EC) 258/97 was very similar to the Directive 90/220/EEC in terms of assessment and introduced a mandatory premarket safety assessment for all novel foods (MOSELEY, 2002).

With this development in the legislation the gap for GM food approval was getting smaller. Furthermore, revolutionary change was that the applicants could apply not only for environmental release of GM products, but also for GM products for food purposes.

In the following text you will find the approval procedure within the European Union for novel foods and ingredients.
According to Article 4 from the Regulation, the applicant shall submit a request to the Member State, where the product will be placed for the first time. According to Art. 6 from Reg. (EC) 258/97, the application should consist of study carried out in advance. Then the Member State should perform an initial assessment. The assessment should be drawn up within three months from the receipt of the application. The Member State, where the assessment is done, has to forward the report to the Commission and within 60 days the

[10] Genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

[11](c) foods and food ingredients with a new or intentionally modified primary molecular structure;
(d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods
or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Commission has to make a decision. If no objections are appealed from one or more Member States the latter procedure is applied, but if objections are appealed two-step procedure comes into force. In the first case, risk assessment would be carried out by the initial Member State and others are informed of the decision via the Commission. If two-step procedure has to be applied the Scientific Committee must step in and take action. Once the product is approved, it can be placed in the entire EU market (European Commission, 2000).

A key point in the new regulation is Article 8, where the requirements of Community law concerning novel food labelling is explained. The Article ensures that the final consumer will be informed about the characteristic of the novel food and the ingredients:
"*Article 8*
1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:
(a) Any characteristic or food property such as:
- Composition,
- Nutritional value or nutritional effects,
- intended use of the food,
Which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient." (Europa E. , http://eur-lex.europa.eu, 1997)

Based on the new regulation, which was adopted, it can be said that overall practical effectiveness and credibility of GM regulation had been improved a lot, but still some gaps remained (Homeyer, 2001).

Consequently Dir. 90/220/EEC and Reg. (EC)258/97 were governing GMOs in the environment and GM foods until the year of 2001, when the directive was amended.
On 12 April 2000, European Parliament adopted 29 amendments on revised Directive 90/220/EEC. The amendments are towards the following changes in the legislation:

- better efficiency and transparency;
- high level of protection of human health and environment;
- clarifying scope, some definitions and administrative procedures;
- better harmonisation in aspect of risk assessment;
- development of the role of the Scientific Committees;
- improvement in area of the decision making and authorisation process;
- stricter measures on labelling and traceability (Europa E.)

In 2000, the adoption of Cartagena Protocol[12] led to significant changes in the Food Law. The scope of the Cartagena protocol is related to modified living organisms and how they are handled, taking into consideration environmental protection as well as human health (Diversity, 2000).

[12] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.
Available online at: http://bch.cbd.int/protocol/background/ (last viewed on 24/09/2013)

2.2.3 Directive 2001/18/EC

On March 12, 2001, the new Directive 2001/18/EC was adopted. It is based on Dir. 90/220/EEC with amendments in terms of objective, definitions as well as the assessment procedure itself.

The directive describes two procedures; the first one is for deliberate release into the environment, i.e. research purposes and the second one is for selling of GMOs, i.e. consumption of GMOs either grown in the European Community or imported (Corti-Varela, 2007)

The legislation provides general regime to release GMOs, caring out risk assessments, having requirements and strict regulatory approval procedures. Later, these stricter requirements were prolonged to labelling and traceability regulations (Wong, 2003).

The objective of the directive is to protect human health and the environment when releasing GMOs out into the environment or placing them on the market as such products within the Community. Below each step of the application procedure is outlined.

Upon receipt of the application, the following steps are expected to be taken within the following deadlines:

Action	Deadline	Article
Submit notification to competent Authority in one of the Member States	-	Art. 13
Competent Authority shall prepare an assessment report	90 days (+15 days)	Art. 14
Competent Authority or the Commission may ask for further information	60 days	Art.15
Competent Authority and the Commission may discuss any outstanding issues	105 days	Art.15
Competent Authority shall inform the other Member States and the Commission of the final decision	30 days	Art.15
Commission shall make the proposal available to the public, so public may comment to the	60 days	Art.16

Commission		
The consent is given for max of 10 years. The approval procedure can be terminated in any of these steps from the competent authorities, if the GM product is found to be unsafe for the environment or humans.		

Figure 2 The approval procedure of GMOs in the European Union according to the Directive 2001/18/EC

The application starts with the notification procedure, explained in Art. 13. Then the assessment report is prepared by the competent authority, where the report shall indicate if the GMO in question is approved to be placed on the market or not. In Art. 15, details for further discussion and the time frame are explained. In Art. 17, it is explained the renewal of the consent. It should happen at least nine months before the expiry date of the consent.

Another significant change in the new directive is the labelling requirement. It is explained in Art. 21 and makes explicit that the Member States should ensure that labelling and packaging of the product complies with the requirements.

In Art. 22 free circulation is explained. It says, that, “Member States may not prohibit, restrict or impede the placing on the market of GMOs, which comply with the requirements of this Directive” (Commission, eur-lex.europa(Dir 2001/18/EC), 2001). This procedure is unique, because it ensures the free circulation of all GMO products within the Union.

Even though free circulation of goods is ensured there are some exceptions, which can be applied by the Member States. One of these exceptions allows free choice of the Member State, if GMO products can be released in the territory or not. This is explained in Article 23, which is also so called ‘Safeguard clause’. On basis of this clause, a Member States can restrict or prohibit the use or sales of GMOs or in a product in their territory, whenever new information or reassessment of existing information suggests that GMO constitutes risk for human health or the environment (Corti-Varela, 2007). Later, this measure will be discussed in further detail.

From everything said above, it can be concluded, that, the new authorisation procedure under Directive 2000/18/EEC is detailed and complicated, because National Authority proposal is required as well as a positive report from the European Food Safety Authority. Additionally, a qualified majority in the European Council has to be in favour of the decision. The lack of the last requisite was the major reason for de facto moratorium between years 1999 and 2004 (Corti-Varela, 2007).

In summary, to commercially cultivate a GM crop it should be authorised for placing on the European market under Directive 2001/18/EC and registered in a national or common catalogue of varieties in order to get access to the GM market.

2.2.4 Regulation (EC) 1829/2003

Regulation (EC) 1829/2003 provides legal basis for the market approval process on genetically modified food and feed, including the ingredients, additives and enzymes.

The objective of the regulation is to ensure high level of protection of human life, animal health and welfare, environment and consumer interests in relation to genetically modified

food and feed and ensuring effective functioning of the internal market (European Union, 2003).

As it is explained in Art 3 of the regulation, it is applied to:
"(a) GMOs for food use;
(b) food containing or consisting of GMOs;
(c) food produced from or containing ingredients produced from GMOs" (European Union, 2003)

Upon receipt of the application, the following steps are supposed to be taken within the following deadlines:

Action	Deadline	Article
An application for an authorisation should be send to a National Competent authority of a MS	-	Art. 5
The National Competent Authority shall: **1) acknowledge a receipt of the application** **2) inform EFSA**	14 days	Art. 5
Competent Authority shall inform the other Member States and the Commission	14 days	Art.5
The Authority shall give an opinion	6 months from the receipt	Art.6(1)
Authority may require additional information in order to make a decision	3 months after the date of receiving the request	Art.6 (4)
Commission shall submit the decision taken to the Committee	3 months after receiving the opinion of the Authority	Art. 7
The consent is given for max of 10 years. The approval procedure can be terminated in any of these steps from the competent authorities, if they find the GM product unsafe for the environment or humans.		

Figure 3 The approval procedure of GMOs in the European Union according to the Regulation (EC) No. 1829/2003

As it is said in Art. 5 of the regulation, the Authority shall make the summary of the dossier with the information available to the public.

The new legislation seems to be very similar to the previous one, but in some points is clearer and more precise. The main goal of the Regulation (EC) No. 1829/2003 is to strengthen labelling and traceability requirements. (Sindico, 2005).

In Section 2 of the Regulation, labelling requirements are set. Article 12 of the legislations says, that labelling requirements are set for foods produced from or consisting of GMOs in proportion more than 0.9% of the total amount of ingredients (European Union, 2003).

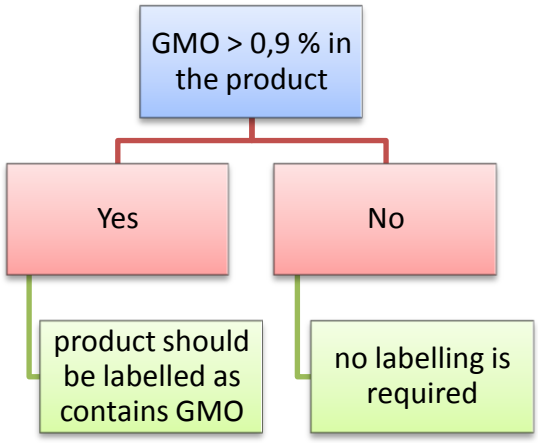


Figure 4 Decision tree for labelling of GM food products

Regulation (EC) 1829/2003 ensures centralised, uniform and transparent procedure for GMO application. It concerns not only the GMO itself, but also the product derived from it (Kuiper & Davies, 2010).

With this new regulation, the European Community brings new criteria for authorisation procedure on GM food and feed as:

1) food/feed produced from GMOs;
2) food/feed containing or consisting of GMOs;
3) food containing ingredients produced from GMOs (Kuiper & Davies, 2010).

In addition, Regulation 1829/2003 is more precise and refers to Regulation 1830/2003 on traceability and labelling of genetically modified. One of the major point, which differs from Directive 2001/18/EC is the appropriate post marketing monitoring on GMO food for human consumption and animal feed was introduced, too (Kuiper & Davies, 2010).

Another important point is the involvement of EFSA in the GMO authorisation procedure. According to Regulation 1829/2003, GMO food/feed is scientifically evaluated by EFSA. EFSA's core task is to independently assess any possible risks of GMOs to human and animal health and the environment. EFSA does not authorise GMOs, which is done by the European Commission and Member States in their role as risk managers. EFSA's role is strictly limited to giving scientific advice. The next step is to carry out the environmental risk assessment, by EFSA or other component authority (Kuiper & Davies, 2010).

2.2.5 EFSA's role in the authorisation procedure

The schematic overview of the 2 authorisation procedures, under Directive 2001/18/EC and Regulation 1829/2003 can be found below.

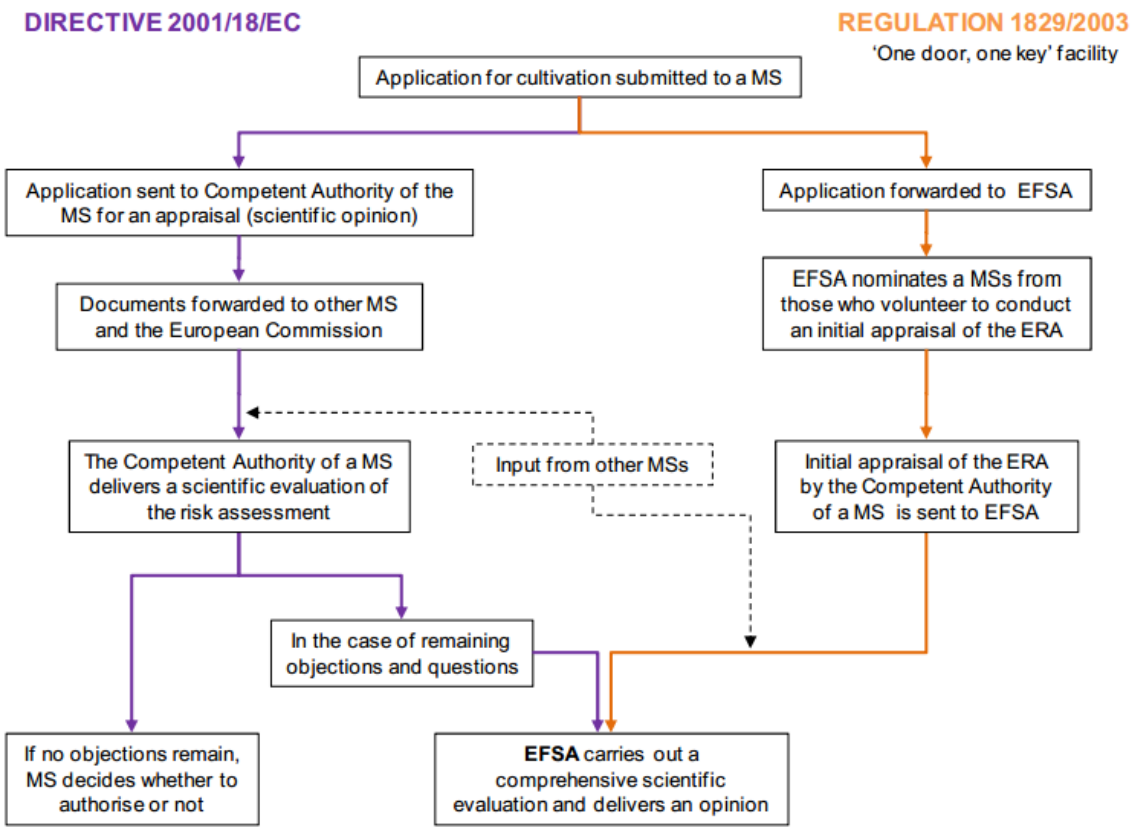


Figure 5 Flow chart on GMO authorisation, where EFSA's involvement is illustrated [13]

The major difference in the authorisation procedure itself is the involvement of EFSA as risk assessment body. In case of the Directive 2001/18, it may never happen. The input of EFSA is requested only if MSs object on the decision taken by the Commission. As it can be seen from the scheme above, the Commission takes the decision based on the risk assessment report prepared by one of the MSs. EFSA is involved only if the objections are raised by Member States and cannot be resolved. Then EFSA is asked to provide an opinion within 90 days focusing on the scientific divergences between the MSs.

In the case of Regulation 1829/2003, EFSA takes centralised position in the evaluation. The risk assessment is carried out only by EFSA and the opinion delivered to the EU Commission within 6 months, if a request for additional information is not made. In case, the application includes the cultivation of GMO, a MS must perform environmental risk assessment. Still, EFSA finalises the full risk assessment to form the scientific opinion.

[13] Factsheet by EFSA, http://www.efsa.europa.eu/en/home/publication/Factsheet_GMO_frameworkv4.pdf (last accessed on 04/12/2014)

3. “One door, one key principle”

In this chapter so called “one door, one key principle” for GMO authorisation will be explained. First, the scope of the principle will be analysed into details and then the current situation with approvals will be monitored. In the end, GM Amflora potato case will be explained, as well as the court case of Pioneer (GMO producing company) versus the European Commission.

3.1 The scope of the principle

To protect humans health and animals welfare Regulation (EC) No.1829/2003 and Directive 2001/18/EC govern authorisation of GMO food and feed, as well as their deliberate release in the environment. There are several angles to look at this principle[14].

The first approach is so called “single application”. Under “one door, one key principle” single application has to be filed by the business operators in order to obtain authorisation for genetically modified food and feed uses and cultivation at the same time.

The second approach refers to only one risk assessment under Regulation (EC) No. 1829/2003; consequently 1 application will be filed to obtain 2 types of authorisation.
The principle covers GMOs for food and feed uses (as first scope of the application, where the imports are included) and GMOs for deliberate release into the environment under the GM Food and Feed Regulation (as second scope of the application), which does not require separate authorisation under Council Directive 2001/18/EC.

The authorisation procedure covers the following types of foods:
-Food containing or consisting of genetically modified plants;
-Food produced from genetically modified plants or containing ingredients produced from genetically modified plants;
- Feed containing or consisting of genetically modified plants;
- Feed produced from genetically modified plants;
- Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation;
- Seeds and other plant propagating material for cultivation in the Union.
In this way the ”Regulation (EC) No 1829/2003 lays down Union procedures for the authorisation and supervision of genetically modified food and feed, including rules for the labelling of such food and feed”[15]. It’s implementing regulation (EU) No 503/2013

[14]For a food or feed product containing GMOs or consisting of such organisms, the applicant has a choice: either file the application exclusively under Regulation (EC) No. 1829/2003 pursuant to the "one door, one key" principle in order to obtain an authorisation for the deliberate release of a GMO into the environment — in accordance with the criteria established by Directive 2001/18/EC — and the authorisation to use this GMO in food and feed — in accordance with the criteria established by Regulation (EC) No. 1829/2003; Or, the applicant can choose to split the application, and submit it both under Directive 2001/18/EC and Regulation (EC) No. 1829/2003.Available on the internet at:
http://ec.europa.eu/food/food/biotechnology/qanda/b2_en.htm (last viewed on 29/09/14)

of 3 April 2013 is providing more comprehensive and systematic rules and information for the assessment (Food Standard Agency U.K, 2004).

The authorisation procedure involves only one dossier and one scientific risk assessment for the authorisations carried out by EFSA. The outcome of EFSA's report is forwarded to the EU Commission, where commissioners as risk managers take the decision. The responsibility of risk regulation is shared between all the Member States and the Committee (Vos & Everson, 2008).

Experts of "GMO Panel" perform the scientific risk assessment for each application. EFSA prepares its opinion on the basis of these analyses together with competent authorities (Grossman, 2009). The scientific opinion is a risk assessment, which is based on molecular characterisation of the GMO product, afterwards comparative analyses is done. Next step is food/feed safety assessment, where relevant scientific data is evaluated. This step includes toxicological assessment, allergenicity assessment, nutritional assessment and conclusion is drawn. The last step is the environmental risk assessment and monitoring plan for the uses of this specific GMO food, feed or plant (EFSA, 2013).

The priority of this approach is focused on human health and minimising the risk to humans, animals and the environment. The regulation ensures misleading of the consumers not to appear, as well as nutritional disadvantage for the consumers (Fernando-Macvean C. , 2013)

Field trials of GMOs are done on case-by-case basis and in accordance with step-by-step principle. Case-by-case principle means that GMOs are assessed individually for each uses, so each authorisation is judged separately and therefore the risk is assessed on basis of the nature of specific uses of that GMO. Step by step approach means that each GMO is approved for each step and use individually and the next one depends on the previous ones.

In order to fulfil these requirements, the applicant may follow Implementing Regulation 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No. 1829/2003. This binding regulation was made to give more detailed information to the applicants. The Regulation 503/2013 itself is more explicit and detailed compared to Reg. (EC) No. 1829/2003, which gives the applicants an opportunity for better preparation of their authorisation file.

EFSA's role in this legislation makes the whole process more centralised and leads to a more sectorial approach. With this principle based on Regulation (EC) No. 1829/2003 the role of EFSA has increased tremendously. Compared to earlier stages, GM legislation was more horizontal and no competent body was directly responsible for harmonization and authorisation of GMOs (Grossman, 2009). This procedure turned out in benefit of EU free trade market and made Member States accept each other's risk assessments (Fernando-Macvean, 2013).

Before applying for the specific authorisation, the applicant should follow guidelines for the risk assessment from EFSA and submit all the documents according to them.

[15] COMMISSION IMPLEMENTING REGULATION (EU) No 503/2013, this is the definition for Reg. (EC) No. 1829/2003, (1) OJ L 268, 18.10.2003, p. 1.

By filing a single application, single risk management process involves both the Commission and the Member States throughout a regulatory committee procedure. (Meulen, 2009).

On the other hand, i.e. via mutual recognition "one door, one key principle" is valid throughout the whole European Community. The applicant submits the application to national competent authority of a Member State and if the authorisation is granted by the European Commission, it is valid throughout the whole European Union. In other words, the applicant doesn't have to file separate application for each country in the European Union (Meulen, 2009).

The core stone of the principle is that if the applicant is filing one application under Regulation (EC) No. 1829/2003 requesting both types of authorisations (for feed /food uses as first one and cultivation as second one) there will be only one answer based on the risk assessment for both types authorisation. If EFSA's opinion is negative, then the authorisation will not be granted, because it would be considered as one application for which the European Commission makes one decision.

As a conclusion it can be said that if "one door, one key principle" is used, then only one decision will be made. It leads to the fact that the GMO will be authorised, only if the applicant goes through "one door, one key principle" with Regulation (EC) No. 1829/2003 for both types of authorisation and obtains the approval or the authorisation is not granted at all.

The authorisation is granted for 10 years period and it is renewable after 10 years. At the same time, it is a subject to post-marketing monitoring. The latter can be explained as via the Regulation (EC) No. 1829/2003, which places an obligation between producers. If scientific evidence comes to light, they have to inform the Commission about the product safety. That will ensure continuous consumer protection. If the post marketing monitoring shows any risk for consumers, the authorised GMO can be cancelled. Later in this paper the case with Amflora potato is discussed. First, the GM potato was authorised and on 13 December 2013, the General Court cancelled the European Commission's decision on authorisation of the Amflora potato[16]. More detailed information can be found in the next chapter of the paper.

3.2 The current situation of the approval procedure and the choice for approval products by the businesses

In the following paragraph, information about the regulation for an authorisation will be given. Secondly, the time for the authorisation process will be discussed. Additionally, it will be described how the authorisation procedure works.

[16] JUDGMENT OF THE GENERAL COURT
Available on the internet at
http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d6ee7f2a8564a646dbb2aede76a8e616cb.e34KaxiLc3qMb40Rch0SaxuOb3r0?text=&docid=145620&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=252048 (last viewed on 24/09/2014)

Based on the information on EFSA's webpage[17] it can be concluded that all of the applicants go through Reg. (EC) No. 1829/2003 for GMO product approval. Thus, in practice the Directive 2001/18/EC is fully replaced by the regulation, which supports the theory of the European Commission and in terms of the legislation "one door, one key principle exist", where both food/feed uses and cultivation are regulated by Reg. (EC) No.1829/2003.

Remarkably, according to the database, it seems that the principle is not very often used in terms of obtaining an authorisation for food/feed uses and cultivation at the same time. The applicants use the legislation for an authorisation for food and feed uses and imports and processing. In this respect, none of the applicants use the principle to obtain an authorisation for cultivation.

According to the information obtained from EFSA's webpage[18], applicants who file an application are mostly seeking an approval for importation or processing.
The applicants do not apply for cultivation of the GMOs in the territory of the European Union; hence the authorisations for cultivation are not assigned by the European Commission.

In the next paragraph the legal time for an authorisation will be a subject of the discussion. Regulation (EC) No. 1829/2003 can be divided into 3 steps in terms of the procedure:

- Submission of an application
- Preparation and delivery of an opinion by EFSA
- Preparation and adoption of a decision

The first point indicated above, should not take more than 14 days, according to the regulation. EFSA's opinion, which is the second step of the assessment procedure, is that it shall not take more than 6 months, if the applicant provides all the information. For the last step, where the Commission has to submit a draft decision, the time limit is 3 months. The Commission then has to pass on the decision to the Standing Committee. If the latter doesn't accept the proposal, then the Council has to make a decision within three months for the proposal.

If the outlined procedure is followed, the authorisation should not exceed 10 months (Directorate-General for Agriculture and Rural Development, December 2010).The situation in practice is quite different. As it can be seen from the database of EFSA's website, the average duration of GMO authorisation application for 2012 takes 45 months including risk assessment and processing safety assessed dossiers to the votes by Member States.

According to data provided by Europabio[19], EFSA's review and opinion takes in average 30 months. The average time of the Commission processing the Member state voting is circa

[17] Available on the internet at http://registerofquestions.efsa.europa.eu/roqFrontend/?wicket:interface=:2 (last viewed on 29/09/14) -EFSA's website, where all the questions are registered. On this webpage, information about the GMO approval submissions can be found.
[18] Available on the internet at http://www.efsa.europa.eu/ (last viewed on 29/09/14)
[19] EuropaBio is board of management made up of representatives of member companies. The board is supported by the EuropaBio secretariat who carry out day to day activities and is managed by a Secretary General. The three main segments of Biotechnology are represented through sectorial councils: Healthcare (Red Biotech), Industrial (White Biotech) and Agri-Food (Green Biotech). Available on the internet at http://www.europabio.org/how-we-are-organised (last viewed 29/09/14)

16 months. Based on this information, the European GMO authorisation system seems to be very slow, that leads to a backlog of products in the system and the number is increasing with the years.

According to EFSA's database, between 2008 and 2012, for each year the number of the applications pending has increased. The difference between the applications submitted and authorisations received is significant. For example, in 2008, nine applications were submitted and only four authorisations were received. In the next years, from 2009 until 2012, the same trend can be observed. Further details can be found on following table[20].

Year	2008	2009	2010	2011	2012
Applications submitted	9	12	13	14	8
Authorisations received	4	5	11	7	6

Figure 5 Number of the applications submitted and the authorisation received under Regulation (EC) No. 1829/2003

The big difference between the numbers of the authorised GMOs and the applications received, leads to delays in the approval procedure. At the same time the applications in the pipeline are increasing each year. Consequently, it takes much longer for the applicant to get approval for the GMO product and the deadlines are shifting. In some of the cases, the applicant is losing interest in getting an authorisation for the product, because it is not relevant anymore as a new product to launch on the market. For example, a product, which had been created 4 or 5 years ago is not suitable for the current market, which is very dynamic and changing constantly its needs.

Another outstanding point of the data from EFSA's records is that companies do not apply for cultivation authorisation anymore. Based on this, it can be concluded that the current applicants use Reg. (EC) No. 1829/2003 mostly for food and feed uses and the imports, but not for cultivation purposes.

➢ Amflora Potato Authorisation Case[21]

Amflora potato is one out of two GM plant authorised for cultivation. The authorisation is granted in 2010. As briefly discussed in chapter 3, Amflora starch potato (EH92-527-1) and Mon 810 Maize are the only GMOs in European Union authorised for cultivation as of 13 December 2013.

[20] Available on the internet, at: http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?unit=GMO (Last viewed 29/09/14)

[21] The General Court's decision Available on the internet at http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d6ee7f2a8564a646dbb2aede76a8e616cb.e34KaxiLc3qMb40Rch0SaxuOb3r0?text=&docid=145620&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=252048 (last viewed 24/09/2014)

On 27 May 2010, there was an action brought from Hungary against the European Commission, where Austria, France, Luxembourg and Poland supported Hungary for annulment of the Commission's decision. Hungary and the other Member States claimed that the Commission deviated from the rules of the authorisation procedure.
In other words, BASF[22] applied for authorisation for cultivation, where EFSA had to make the risk assessment. In 2005 EFSA submitted a favourable Risk Assessment report, but the Commission did not grant an authorisation. Instead the Commission decided to consult EFSA again, because the Commission had received information concerning inconsistencies between different scientific opinions. The outcome of the new report outlined minor conflicting opinions. Based on the new information, the EU Commission didn't release the new draft decision and the authorisation was granted by 2nd of March 2010.

Following this decision, the Commission did not comply with the rules of the Regulation (EC) No. 1829/2003 and granted the authorisation. If the minor changes were done on the new draft, the decision would have been substantially different.

The General Court concluded that the Commission failed to fulfil the obligation and annulled the contested decision.

As an outcome of Judgement of Case T-240/10 Hungary v European Commission, in terms of GMOs allowed to be cultivated in European Union, there is only one as of January 2014 and it is Maize 810 by Monsanto.

- **Pioneer versus European Commission[23]**

Case T‑164/10 is between Pioneer (one of the leading biotechnology companies) versus the European Commission. The applicant for the case is Pioneer, who claims that the European Commission failed to submit a draft decision to the Council. Pioneer had applied for an authorisation to place a GMO called insect resistant genetically modified maize 1507 for cultivation on the market under Directive 90/220/EEC of 23 April 1990 on deliberate release into the environment.

On 26 September 2013, The General Court decided "that the European Commission has failed to fulfil its obligations under Article 18 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC by failing to submit to the Council a proposal relating to the measures to be taken pursuant to Article 5(4) of Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission"[24] (Approximation of laws – Deliberate release into the environment of genetically modified organisms – Authorisation procedure for placing on the market , 2013).

[22] A chemical Company, who received the authorisation of the GMO potato.
[23] Available on the internet at http://curia.europa.eu/juris/document/document.jsf?text=&docid=142241&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=798980 (last viewed 29/09/14)
[24] Court case between Pioneer Hi-Bred International and European Commission, Available on the internet at http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&pageIndex=0&part=1&mode=DOC&docid=142241&occ=first&dir=&cid=199705 (last viewed 29/09/14)

This case indicates that the European Commission had been too slow to propose allowing the cultivation of the product Pioneer applied for.

The next step of the procedure is that the Commission should pass the decision onto the Council of Ministers, where the majority for or against the decision should be made. From the statement[25] by the EU Health Commissioner Tonio Borg, on the Commission's decision on GM Pioneer 1507, the Council of Ministers of the Environment should have made the decision. Even if the answer is positive, it does not mean that all the Member States should allow the cultivation on their territory. They can still refuse it on basis of pedigree subsidiarity. In the following table the list of the countries that have banned GMO cultivation is presented.

Germany
Austria
Hungary
Bulgaria
Luxembourg
France
Switzerland
Greece
Italy
Poland
Romania

Figure 6 List of the countries banned cultivation in their territory

Austria, France, Greece, Hungary, Luxembourg, Poland and Romania are the countries who have a strict ban on cultivation of Mon 810 maize. The other countries have a general prohibition for GMO cultivation on their territories (unknown).

[25]Statement by EU Health Commissioner Tonio Borg, on Commission's decision on GM Pioneer 150, Available on the internet at http://europa.eu/rapid/press-release_MEMO-13-960_en.htm (last viewed 29/09/14)

4. Data analyses

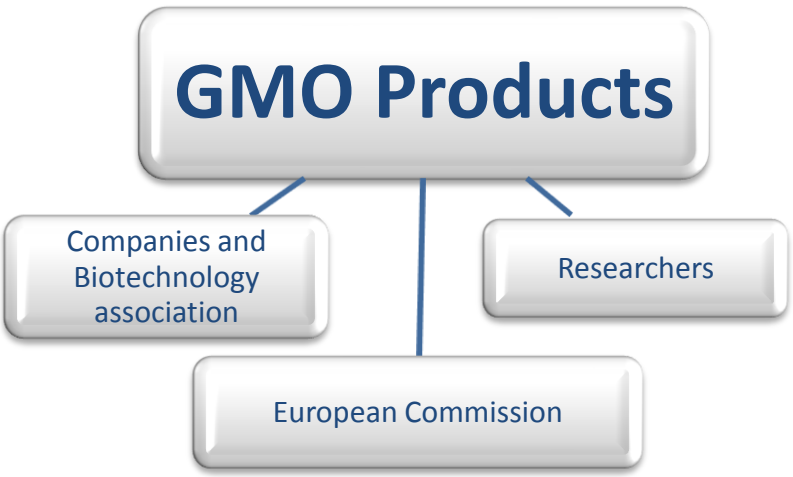
In this chapter, the results of the empirical research will be presented. The research consists of interviews with companies applying for GMO authorisation, the European Commission and independent researchers.
The list of contacts is presented in the table below:

Monsanto
Syngenta
BASF
Pioneer
Bayer
Niaba Dutch biotechnology association
EuropaBio (European Biotechnology association)
Solynta
European Commission
Pim Lindhout- independent researcher from Wageningen University
Ellen Vos- prof. dr. From University of Maastricht

Table 1 Contacts for the interviews

The purpose of the interview was to answer the question if “one door, one key principle” does exist. The question will be answered via personal interviews and their experience with the principle. The full list of the contacts can be found in Annex1 with an explanation if they have responded or not. The full text of the questions and the criteria for grouping the questions can be found in Annex 2.

The participants are divided into 3 groups:



4.1 Interviews with companies

Companies were selected on the bases of their experience with the GMO authorisation procedure. The Questions are related to the authorisation procedure and their experience with it. In the following table you can find the questions addressed.

1. What type of GMO product are you dealing with?
2. What type of authorisation procedure did you follow Regulation (EC) No. 1829/2003 or Dir 18/2001?
3. What type of authorisation did you want to acquire (food/feed uses or environmental release)?
4. Why do you specifically prefer that one and not the other one?
5. Why did you choose or didn't choose the "one door, one key principle"?
6. When did you apply for an authorisation and how long it took?
7. When you were making the choice for the procedure what did you take into account?
8. Did you think about risk spreading?
9. How much were the monetary costs involved in your authorisation procedure?
10. What was the impact of the "one door one key principle" for you as a company?
11. What are the advantages of this procedure for your company?
12. What are the disadvantages of this procedure for your company?

Table 2 Interview questions for the companies

There were 2 companies Syngenta and Bayer, who agreed to conduct an interview to answer the questions for the research. The interviews took place in their main offices in Brussels, Belgium.

With each interviewee the procedure for GMO authorisation was discussed. They shared their experience with the procedure and GMO products they are dealing with. Bayer replied to the first question of the interview that the company is dealing mainly with crops such as corn, soybean, rice, cotton and canola, which are herbicide tolerance, insect resistance and hybrid traits. Syngenta is dealing with cotton, soybean, rice and insect resistant corn.

The answer for question No.2 from the table for all the companies, i.e. Bayer and Syngenta, was that they have been using Reg. (EC) No. 1829/2003 for food and feed authorisation purposes. Regarding question No.3 about the authorisation type they were willing to acquire, the companies replied that they are mainly willing to get an authorisation approval for processed food and feed for certain GMOs and GMOs for imports.
According to the results of the interviews with Bayer and Syngenta the answer to question No.4 is that they don't apply for cultivation authorisation for their GMO products anymore. It

is due to the fact that no authorisation for cultivation has been granted recently. After the case Pioneer versus the European Commission (December, 2013), where the European Commission failed to submit the draft decision, companies have become more sceptic if they will get an authorisation for cultivation purposes or not, and therefor don't see the necessity in applying for it.

The answer for question No. 5 is that companies apply via Regulation (EC) No. 1829/2003, but are not making use of the "one door, one key principle", that is because the answer for both types of authorisation should be given as only one. In fact if EFSA's opinion for imports is positive and cultivation negative, there should be only one answer formulated. Therefore a negative answer is more likely to be received.

In question No. 6, Syngenta and Bayern were asked how long the authorisation procedure took when they applied for it. Both interviewees replied that the authorisation procedure for cultivation in practice takes more than 10 years and the authorisation for imports takes approximately 3,5 years.

Question No.7 is related to the choice of the procedure and what was specifically taken into account when companies were applying for the authorisation. According to the results both of the companies took into account that the authorisation procedure is too long. If the risk assessment for imports is ready, the risk assessment for the cultivation has to be finished too and one final report should be prepared. Economic profit is also taken into account, if there is no profit the companies would apply only for type of authorisation, which is authorisation for imports most of the times.

Question No. 8 is about risk spreading and how companies deal with it. Both Syngenta and Bayern had their risk spreading analyses in beforehand. Based on this the authorisation application starts.

Question No.9 is related to the monetary costs involved in the authorisation procedure. According to the information from Syngenta, the research time and the costs the company spent for new biotech product and the authorisation procedure was millions of euros. The costs for Bayer are not less than what Syngenta is spending. During the interview, Bayer announced that costs of discovery, development and authorisation of a new biotechnology trait are approximately 100 million euros. These costs are valid for the products launched between years 2008-2012.

With question No.10 the answer for the impact of "one door, one key principle" was received. Bayern answered that the regulation requires diligent follow-up when authorisations had to be renewed and that leads to new challenges to products that have been already launched on the market. Based on all these difficulties companies face, they withdraw their applications very often and the use of the principle avoided.
Syngenta replied that they are not using "one door, one key principle, therefore it doesn't matter for them as such.

In the last two questions advantages and disadvantages of the principle for the companies were discussed. According to Bayer the advantages of the procedure are related to compile

one dossier for all intended authorisation scopes. According to the interview with Syngenta, they don't see any advantage of the principle as such. The main reason is they don't use it.

Bayer doesn't see disadvantages of the principle; the remark made was related to the overall regulatory system in the EU, which does not reflect biological and commercial realities including those of global trade. Syngenta's opinion about the disadvantages of the procedure is that it is too long and in certain stages not useful. The full text of the interviews can be found in Annex 3.

4.2 Interview with the Biotechnology association

EuropaBio is an association represented by members of biotechnology companies. They have first-hand information from their members and during the interview provided more details for the procedure the companies go through.
The questions for the interview with EuropaBio can be found below.

1. Do you have any statistics to show how many applications are sent for GMO Authorisation per year?
2. How many applications are authorised per year (food/feed and deliberate release separately)?
3. Do you think that there is a change since the Reg. (EC) No. 1829/2003 is in force? Could you explain it?
4. Under which legislation the applications are filed? (Reg. (EC) No. 1829/2003 or Dir. 2001/18/EC)
5. Why do the companies prefer the one you answered on the previous question and not the other legislation?
6. Is "one door, one key principle" useful during the authorisation procedure, if yes-why?
7. Which guidelines are used for GMO authorisation?
8. How long does it take for a company to get an authorisation for Deliberate release and for Food and Feed uses (separately and together)?
9. How do you see the current legislation for GMO authorisation?
10. Why do you think there are more than 60 GMOs for food and feed use authorised and only 2 for cultivation?
11. What are the advantages of "one door, one key principle" for the companies?
12. What are the disadvantages of "one door, one key principle" for the companies?
13. How do you see the future plans of the Commission for GMO authorisation? Is there room for improvement?

14. What do you think about the proposal of the European Commission to grant Member States more subsidiarity on cultivation?

Table 3 Interview questions for Biotechnology association

EuropaBio answered to the first question that there were 9 submissions for 2013 via Reg. (EC) 2003/1829. They have reported that for next year, 10 renewal submissions are expected for previously authorised products. It is expected to be followed by 6 renewal submissions each year.

With question No2, the authorisations granted for biotech products were discussed, EuropaBio reported that circa 5 to 6 food and feed authorisations are authorised for imports. They have also noted that it takes approximately 49 months.

The third question to EuropaBio was related to the changes after the introduction of the new Regulation (EC) No. 1829/2003. It was said that there are no significant changes in terms of authorisation. According to the biotechnology association the Commission's decision is now taking longer than the risk assessment.

With question No4, the association was asked was in relation to the companies preferences for the procedure they go through. It was answered that all the companies prefer to apply under Reg. (EC) No. 1829/2003, rather than Dir. 2001/18/EC.

To the next question No5, where more details were asked about the company's preference in terms of the authorisation, the interviewee replied that due to the deadlock in the authorisation procedure, GMOs are not getting cultivated and the companies are interested more in imports than in cultivation authorisation.

In the next question No6, the usefulness of the "one door, one key" procedure was discussed. From the interviewee's answer it was noted that GMO's are not authorised for cultivation as for imports, therefore the interest for cultivation application is not the same as for imports. This led to fewer applications in authorisation for cultivation.

In question No7, the guidelines used by the companies were discussed. Their reply was that the companies use EFSA's guidelines.

The following question No8 was related to the authorisation time for different types of authorisation. It was answered that the food and feed authorisation procedure takes approximately 49 months, while cultivation takes more than 84 months.

In question No9, EuropaBio was asked to comment the current legislation for GMOs. It was discussed that the cultivation procedure doesn't work as it is. The European Commission also doesn't obey the deadlines set to make a decision.

EuropaBio was asked furthermore to comment about the differences in the numbers between authorised GMOs for food/feed and cultivation, which was actually wuestion No10. It was concluded that if cultivation authorisations are not granted, it has to be compensated with food and feed uses and imports. The lack of any type of authorisation will lead to trade disruption, which should be avoided by the European Commission.

Question No11 and No12 were related to the advantages and disadvantages of the "one door, one key" procedure. As an advantage it has been reported that the EU level of authorisation and easy access of the working language has been improved. As a disadvantage – nothing was indicated.

With the answer of question No13, EuropaBio commented that they don't see direct signs for an improvement in terms of authorisations granted. They also mentioned the political involvement in the risk assessment.
With the last question the proposal of the European Commission for more subsidiarity on cultivation was asked. EuropaBio has certainly expressed their opinion that cultivation in European Union seems to be very far away.
The full text of the interview can be found in Annex 4.

4.3 Interview with the European Commission

The next interview was with the European Commission. As it can be seen from the information provided in Regulation 1829/2003, the role of the EC is the core of the authorisation procedure carried out under the abovementioned legislation. Also, it was mentioned before, that EFSA's role in the procedure is preforming the risk assessment, while the European Commission makes the final decision. The question for the European Commission can be found in the table below.

1. How many authorisations have you granted for GMOs per year?
2. What type of authorisation procedure do companies go through?
3. Why do you think the companies were following that type of procedure?
4. Do they use the "one door one key principle"?
5. How do you make the assessment? Based on scientific risk assessment only or there are also other factors? If so, do you give any advice to the applicants on which procedure to follow?
6. How does the "one door one key principle" influences the EU market?
7. What are the advantages of this procedure?
8. What are the disadvantages of this procedure?
9. Do you have any negotiations with the applicant during the assessment (formal/informal)?
10. What are the future plans?

Table 4 Interview questions for the European Commission

According to the information from the European Commission the answer for the first question can be found in the table below. The numbers of the applicants for GMO authorisation procedure are as follows:

2013	6 (as of November 2013)
2012	8
2011	14
2010	14

Figure 7 Number of Authorisations for GMOs granted by 01.12.1013[26]

From the results in the table, it can be seen that the tendency for granting an authorisation for GMOs is going down.

The second question of the interview is related to what type of authorisation the company aims for; consequently what type of procedure they went through. The Commission answered that applicants go via Regulation (EC) No. 1829/2003, which makes the regulation very applicable and easy for "one door, one key principle". Still, most of the operators go for food and feed authorisation and not for cultivation authorisation.

With the answer for question No 3 the procedure chosen by the applicant was explained. The Commission explained that the route for the application chosen by the applicant is fully dependent on the scope of the application. The Commission added that both applications can be submitted under Regulation (EC) No. 1829/2003 then one answer will be given. When both applications are submitted under the Regulation (EC) No. 1829/2003 and Directive 2001/18/EC a negative answer is more feasible. Otherwise under Regulation (EC) No. 1829/2003 one answer will be given and in the case of a negative answer, the whole dossier is rejected. Based on this, companies don't apply for a cultivation authorisation and the difference in the number of applications appears.

When the commissioners were asked if "one door, one key principle" was used they replied that it is not very often used. It refers to the fact that applicants in practice avoid using the principle. The principle exists to make the application easier and more practical, but realistically it is not used.

The question No 5 related to the assessment and the decision for the authorisation, the commissioners answered that that their assessment is based on EFSA's risk assessment and the decision is independent. They also clarified that there aren't any negotiation between the European Commission and the applicant. The European Commission sometimes would answer questions if contacted, but they don't contact the applicant in relation to the application or the authorisation procedure.

Question No6 is about the influence of the principle on the European market wasn't answered.

In the next answer for question No7, advantages of the principle were discussed. According to the European Commission having the principle in place allows the applicant to change the scope of the application at any stage. This has been seen as very flexible, because with Directive 2001/18/EC it is not possible. The later can be used only for one type of authorisation and the scope covers only that authorisation. Furthermore, the costs to prepare one dossier are lower than preparing two dossiers. This has been seen as a big advantage from a financial point of view.

[26] The numbers are obtained from the Commissioners during the interview

With question No8 disadvantages are discussed. As disadvantage of “one door, one key principle” the Commissioners discussed that the biggest disadvantage seems to be if applications for food and feed uses and cultivation are both made under Regulation (EC) No. 1829/2003 and the decision for part of the scope is negative. If the applicant files one application under Regulation (EC) No. 1829/2003, it means that the answer is valid for that application and not just part of the scope. Therefore if it is negative for one aspect, the overall outcome is negative. Therefore, if something doesn’t go smoothly with one of the assessments, the other one is not going further either.

Question No9 is related to the negotiations between the EU Commission and the applicant. From the question whether there are any negotiations between two parties, the answer from the Commission was negative. For each authorisation a scientific risk assessment is held via the European Food Safety Authority. After the scientific opinion has been published, the procedure enters the risk management phase (EC and Member States authorities are the risk managers). The decision is based on the results of the risk assessment. There are no negotiations held. The only discussion seen as contact can be advice for labelling.

With question No10 future plans were discussed. The EU Commission pointed out that on 13/07/2010, they came up with a proposal for amending Directive 2001/18/EC as regards to the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory or part of it. The proposed amendment aims at providing a legal basis to the Member States to restrict or prohibit the cultivation of GMOs on their territory on grounds other than those based on the assessment of risks to health and the environment - risks which are currently being assessed at EU level.
The full text of the interview with the European Commission can be found in Annex 5.

4.4 Interview with researcher

There was 1 scientific researcher, who responded for an interview and he shared his personal experience and opinion about the principle. The full text of the interview with the Researcher can be found in Annex 6.
The interview questions can be found in the table below:

1. What is your opinion of GMO’s as a researcher with such a solid background in the field of applied Biotechnology?
2. Do you think that “one door, one key” principle is practical and applicable in terms of GMO authorisation on EU level?
3. Do you know why only a few GMO’s are approved for environmental release and much more for feed/food use and imports?
4. Do you know the reason behind the difference in the numbers of these 2 types of approvals?
5. Do you consider the “one door, one key” principle an advantage or disadvantage?

6. What do you think about this authorisation procedure from the perspective of the companies?
7. What do you think is the economic impact of this procedure to the companies?

Table 5 Interview questions for the Researcher

The answer of the first question of the interview was based on personal experience of the scientist. He replied that in 70's when he was still a student he was concerned about GMOs. His biggest concern was the uncertainty about consequences of GMOs in the future. This opinion was based on the scientific knowledge at that time and the risk of GMOs was not yet clear. Over the years he has changed his opinion as his professional experience has developed. Nowadays, his opinion is that genes can have horizontal gene transfer in the nature, therefore genetic modifications happen naturally in the environment. Based on this information the researcher doesn't see risks of one gene transfer, which is the case with GMOs, while in nature hundreds of gene transfers occur. According to the data he has, nowadays 20% of the world's area is planted with GMOs and there isn't any serious disaster related to that. Consequently, it can be noted that the perception of risk in different countries seems to be different.

To the second question of the interview there was no answer given from the researcher. He replied that he doesn't have personal experience with the approval procedure, therefore can't answer this question.

In the third question of the interview, the researcher was asked why only a few GMOs are approved for cultivation and much more for feed/food uses. He replied that the consumers' perception plays a very big role in EU policy making procedure. The EU Commission is influenced by Consumer Organisations and in the European Union citizens' opinion it is as important as science.

To the forth question from the interview concerning 2 types of GMO approvals and the difference in the numbers, the researcher answered that the European Commission wants to limit the cultivation. If GMOs are part of consumers' daily life, it should be based on imports, not on local cultivation.

The answer to the next question, if the interviewee considers "one door, one key principle" as an advantage or disadvantage is not clear. He expressed his concerns about the procedure. Due to lack of personal experience, he cannot analyse the advantages and disadvantages of the procedure itself.

In the next question No6 of the interview, the researcher was asked to give an opinion about the procedure from company's point of view. He said that the authorisation procedure as such is a burden for trade. From a consumers' perspective, the fear from big companies is huge and food is seen also as an emotion. According to the interviewee a minority dictates the rules, because most of the people don't express their opinion, but those who have strong negative opinions express it loudly.

The last question of the interview is about the economic impact of the procedure to the companies. The researcher expressed his concerns for open competition. According to him the choice on the market is limited and opportunities for better business are missing.

5. Discussion and Conclusion

In this section, the discussion about the current law and the results of the interviews will be discussed. Patterns, similarities, relationships and differences between the answers will be explained. Next to that, there will be a closer look on the backstage of the conflicting approval procedure. The possible answers will be drawn and explained.

As it has been already been discussed in the previous sections, current law for GMO Authorisation is fully presented by Reg. (EC) No. 1829/2003. The regulation allows full access to the European market via the authorisation procedure. Depending on the scope of the authorisation, the application can be filed under Reg. (EC) No. 1829/2003 for imports/food and feed uses. If the authorisation concerns only cultivation, it can be filed under the Directive 2001/18/EC. If it is aimed to obtain both types of authorisations, the dossier can be filed under the above mentioned regulation and the directive separately, as well as only under the Reg. (EC) No. 1829/2003 for imports/food and feed uses and cultivation under the scope of “one door, one key principle”. It can be seen as a scheme below:

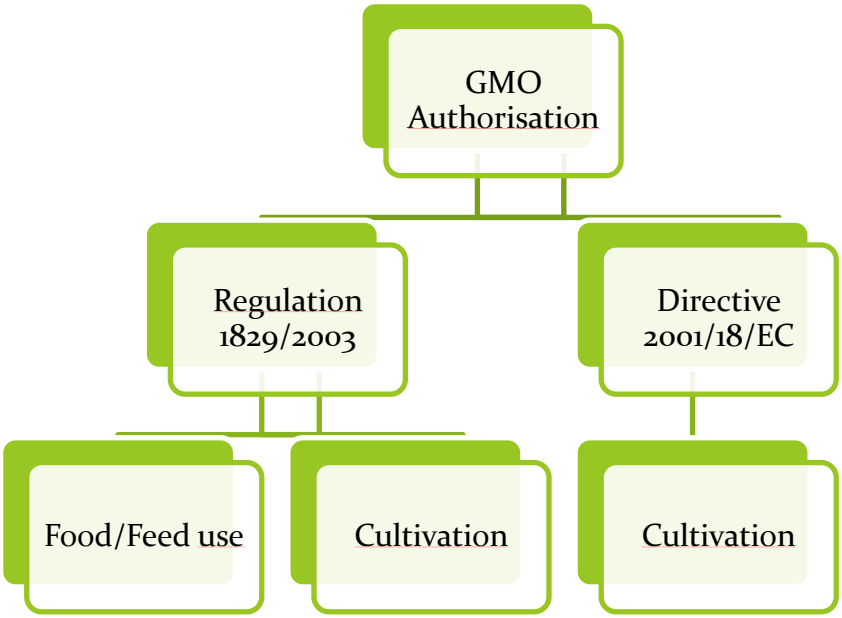


Figure 8 Decision tree for GMO Authorisation

Based on the interviews from all the parties involved and the data collection the following statements have been observed:

1. Most of the companies use only Reg. (EC) No. 1829/2003 for food and feed uses authorisation. They have explicitly confirmed the "one door, one key principle" is not used during the authorisation procedure in order to obtain both type of authorisations. The main reason is that they are more interested in imports of GMOs rather than cultivation. Therefore, additional costs for the authorisation procedure for the cultivation are avoided. The directive does not allow imports authorisation, consequently the dossiers are submitted under the Reg. (EC) No. 1829/2003 and the directive is not used.

2. The companies have been asked about the reasons to apply only for imports and not for cultivation authorisation. The answers have followed the same reasoning. It has been explained that the authorisation for cultivation is rarely granted and based on this; the companies avoid applying for this type of authorisation.

3. Another reason for the avoidance of the "one door, one key" principle as an accession for cultivation is that the authorisation for it takes approximately 10 years. In case of Authorisation for food and feed uses, according to the companies it takes approximately 3,5 years. If the principle is used, both decisions have to be released at the same time and a delay in the cultivation authorisation will exclude earlier authorisation for food and feed uses.

4. Another conclusion based on the interviews is that when the companies are applying for the authorisation they have always been taking into account the economic profit. Most of the time it has been observed that import of GMOs is cheaper and easier than domestic growth, which leads to application of only one type of an authorisation and the "one door, one key" principle is excluded.

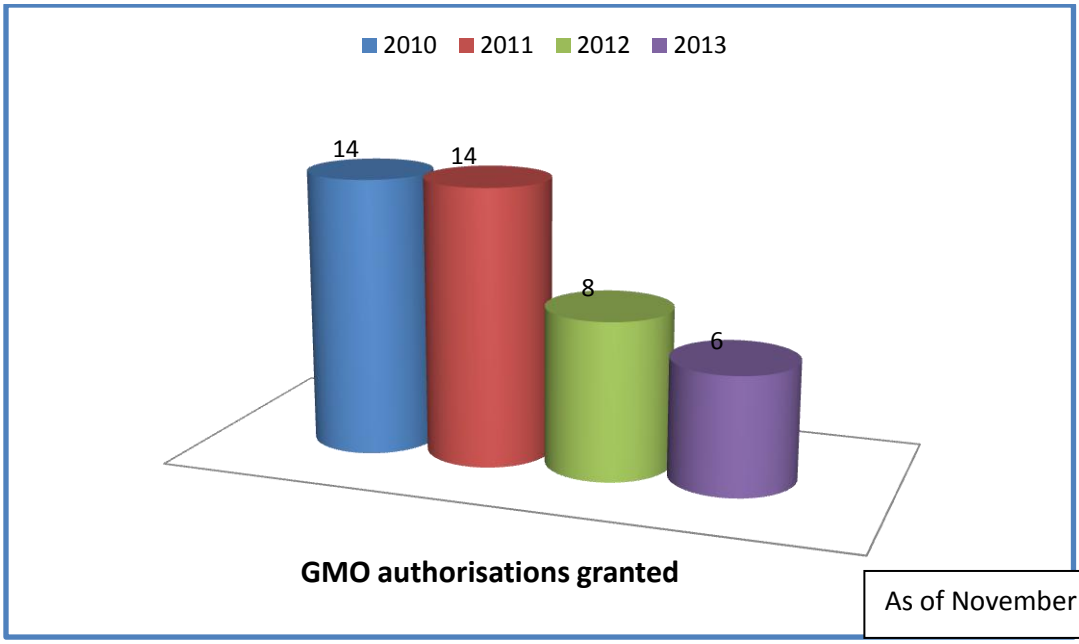
5. A study in Ireland has shown that 25% of the consumers are "anti GM product" and another 20% have "complex reservations" towards GM products (O'Connor, 2006). This has been also approved via the interviews that the interest for cultivation is low due to consumer`s negative perception. This results in lower interest by the companies in using the "One door, one key" principle.

6. There are also a number of cases where the companies are using the "one door, one key" principle. The main reason is filing only one dossier for all intended authorisation scopes. It is easier to follow up and the authorisation costs are lower.

7. During the interview EuropaBio stated that there is a deadlock observed in the authorisation procedure and GMOs are not getting approval. This is another reason why the companies do not use "one door, one key" principle to apply for cultivation as well.

8. The current scope of the Reg. (EC) No. 1829/2003 requires renewal of the authorisation after a period of 10 years. This is also seen as an obstacle by the companies.

9. In the graph below the numbers of the GMO authorisations (for food and feed uses) can be seen. It has been observed that in the last years the number of GMO authorisations granted by the EU Commission are decreasing. In 2011 there were 14 authorisations granted and in 2014 the number decreased by 68%.



As of November 2013

10. In relation to the private sector BASF is one of the leading GM companies, who decided to terminate GM related projects and moved to the US. The main reason behind this decision of the company was the lack of GM demand in EU and the strong anti- campaigns.

11. National bans on GMOs applied in some of the European countries can be seen as illegal under the European single market rules.

12. On 12th June 2014 a statement by Commissioner Borg was released following the Council's political agreement to allow the prohibition of GMO cultivation. This agreement gives the Member States the choice to restrict or prohibit the cultivation of GMOs on their territory.

13. It can be concluded that according to the interviews, the interest in GMO cultivation in the EU is very limited and that leads to lack of authorisation of GMOs for cultivation.

6. Further Developments

In this chapter further developments will be given, explaining the need for transparency and better harmonisation and the path GMO authorisation may take.

Biotechnology is one of the most controversial and hot topics for the last decades in European Union, as well the rest of the world. There are a couple of key elements, making GMOs controversial. On one hand, the economic implications of GMO growth all over the world have a big impact in terms of benefits and competition. On the other hand, the impact on health safety and environmental issues still remains uncertain. The fact of uncertainty leads to different opinions between the consumers and consequently- the policy makers.

The opinion of consumers is also very diverse, depending on the application of the GMOs in different industries. Public perception for GMOs used for agriculture and food is comparatively negative, while there is a tendency of an acceptance of medical application. Consumers are keener to accept products derived from GMO of plant origin when used as medicine, rather than consuming the GMO food product as such.

All this led to a very diverse opinion in the Member States and no common ground has been found in the European Union, because of the differences in the consumers' opinions. This directly affects trade of those agricultural commodities, as well as the local production of those products. In comparison with the US, the EU is definitely behind with GM cultivation and approval procedure. If the approval procedure and the GMOs in EU are compared to other numbers as in US for example, a need for better policy is obvious. The risk of uncertainty, long approval procedure and negative outcome effects the applicants' decisions. Better transparency in the approval procedure is needed, especially with the new political agreement from the EU.

The implications of all those decisions should be better analysed for trade and development of agriculture in EU. A very important point is to find an answer to the following question: Is the EU able to satisfy the future needs with the current regulatory framework? Then the future of the GMOs can be drawn from policy point of view considering the consumers opinion, environmental impact, agricultural development, sustainably and trade.

7. Recommendations

In this chapter recommendations for further research on this thesis topic will be described.

This thesis research was explorative, mainly because not all the parties involved in policy making of GMO authorisation were involved. The research was limited due to limited number of interviews; this led to analysing only the opinion of those who had been interviewed. Therefore, the research should be continued by involving consumer organisations and the European Food Safety Authority to reflect the practical involvement of the authorisation procedure. Even though, many companies, experts and consumer organisations were invited for an interview, it was difficult to get answer and conduct the research. Most of the interviewers were reserved to speak on this topic and required confidentiality. Therefore, the information obtained from them was very limited and not all the questions were always answered. For further research, more detailed information should be obtained with more questions for the interviews, as well as increasing the number of interviewers.

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Annex 1

List of Contacts

Monsanto	Franka Broek (Wageningen, Netherlands). A phone call was made and then e-mail was sent to the person. The reason why Monsanto was contacted was explained. **No reply was received.**
Syngenta	Suzy Renckens was contacted. Interview was conducted in Brussels on 29 November 2013 with Sara Nigro and Angel Fuentes. **You can find the interview in the Annex.**
BASF	BASF was contacted. An emial was sent to global.info@basf.com. Phone call was made, but **no further information** was received from the company.
Pioneer	Pioneer in Germany was contacted. An email was sent with explanation for the interview to piode@pioneer.com. **No further information** was received.
Bayer	Bayer in Germany was contacted. An email with explanation of the thesis was sent. Reply was received from Aneke Schwager from Brussels. An interview with Aneke Schwager was conducted in Brussels on 10th of December 2013. **You can find the interview in the Annex.**
Niaba Dutch biotechnology association	Niaba biotechnology was contacted via phone. An email was sent to vijn@niaba.nl. Due to busy schedule of the professionals, **interview wasn't conducted**. They have forwarded to email to EuropaBio-Brussels.
EuropaBio (European Biotechnology association)	EuropaBio was contacted. Phone interview was conducted on 10th of January 2014 with Delphine Carron. **You can find the interview in the Annex.**
Solynta	Solynta company was contacted. **No reply was received.**
European Commission	European Commission was contacted. DG SANCO represented by Sarah Brown and Kaja Kantorska. The interview was conducted on 29th November 2013 at DG SANCO, Brussels. **You can find the interview in the Annex.**
Pim Lindhout- independent researcher from Wageningen University	He was contacted via emial and an interview was conducted. **You can find the interview in the Annex.**
Ellen Vos- prof. dr. From University of Maastricht	She was contacted as an independent researcher, but **no answer was received.**

Annex 2

Full text of the questions and the criteria for the questions

This group of questions is giving an answer to of what is the experience of the company as such and what type of an authorisation they went through. Based on these answers, the preferred procedure from the companies will be found.	- What type of GMO product are you dealing with?
	- What type of authorisation procedure did you follow Regulation (EC) No.1829/2003 or Dir 18/2001?
	- What type of authorisation did you want to acquire (food/feed uses or environmental release)?
	- Why do you specifically prefer that one and not the other one?
This group of questions is answering if the company makes use of "one door, one key principle" during the application process and why.	- Why did you choose or didn't choose the "one door, one key principle"?
	- When did you apply for an authorisation and how long it took?
	- When you were making the choice for the procedure what did you take into account?
With these questions risk and costs are discussed.	- Did you think about risk spreading?
	- How much were the monetary costs involved in your authorisation procedure?
The impact of the principle is discussed, this will help to answer the future improvements of the principle.	- What was the impact of the "one door one key principle" for you as a company?
	- What are the advantages of this procedure for your company?
	- What are the disadvantages of this procedure for your company?

Questions for Companies:

1. What type of GMO product are you dealing with?
2. What type of authorisation procedure did you follow Regulation (EC) No.1829/2003 or Dir. 2001/18/EC?
3. What type of authorisation did you want to acquire (food/feed or environmental release)?
4. Why did you apply only for one and not the other one? Why do you specifically prefer that one and not the other one?
5. Why did you choose or didn't choose the "one door, one key principle"?
6. What are the disadvantages of this procedure for your company?
7. When you were making the choice for the procedure what did you take into account?
8. Did you think about risk spreading?
9. How much were the monetary costs involved in your authorisation procedure?
10. What was the impact of the "one door one key principle" for you as a company in terms of obtaining both types of the authorisation?
11. What are the advantages of this procedure for your company?
12. When did you apply for an authorisation and how long it took?

Questions for EuropaBio:

1. Do you have any statistics how many applications are sent for GMO Authorisation per year?
2. How many applications are authorised per year (food/feed and deliberate release separately)?

3. Do you think that there is a change since the Reg. (EC) No. 1829/2003 is in force? Could you explain it?
4. Under which legislation the applications are filed? (Reg. (EC) No. 1829/2003 or Di.r 2001/18/EC)
5. Why the companies prefer the one you answered on the previous question and not the other legislation?
6. Is “one door, one key principle” useful during the authorisation procedure, if yes-why?
7. Which guidelines are used for GMO authorisation?
8. How long does it take for a company to get an authorisation for deliberate release and for Food and Feed uses (separately and together)?
9. How do you see the current legislation for GMO authorisation?
10. Why do you think there are more than 60 GMOs for food and feed use authorised and only 2 for cultivation?
11. What are the advantages of “one door, one key principle” for the companies?
12. What are the disadvantages of “one door, one key principle” for the companies?
13. How do you see the future plans of the Commission for GMO authorisation? Is there room for improvement?
14. What do you think about the proposal of European Commission to grant Member States more subsidiarity on cultivation?

Questions for the Commission:

1. How many applicants for GMOs do you have per year?
2. What type of authorisation procedure they went through?
3. Why do you think the companies went were following that type of procedure?
4. Do they use the “one door one key principle”?
5. How do you make the assessment? Based on scientific risk assessment only or there are also other factors? If so, do you give an advice to the applicants which procedure to follow?
6. How “one door one key principle” influences the EU market?
7. What are the advantages of this procedure?
8. What are the disadvantages of this procedure?
9. Do you have any negotiations with the applicant during the assessment (formal/informal)?

Questions for Scientific Researchers:

1. What is your opinion for GMO’s as a research with such a solid background in the field of Biotechnology?
2. Do you think that “one door, one key” principle is practical and applicable?
3. Do you know why only few GMO’s are approved for environmental release and much more for feed/food use?
4. Do you know what can be the reason for the difference in the numbers of these 2 types of approvals?
5. Do you consider the “one door, one key” principle as an advantage or disadvantage?
6. Do you think that it is fair for the companies to follow this difficult procedure and getting an authorisation is like “mission impossible”?
7. What do you think is the economic impact of this procedure to the companies?

Annex 3

3.1 Interview with Syngenta

1. What type of GMO product are you dealing with?
Mainly in Europe we are dealing with GM corn.

2. What type of authorisation procedure did you follow Regulation (EC) No. 1829/2003 or Dir 2001/18/EC?
We are more focusing on authorisation of GMOs for import in European Union and mainly going for authorisation under Regulation (EC) No. 1829/2003.

3. What type of authorisation did you want to acquire (food/feed or environmental release)?
Logically it is for food and feed uses.

4. Why did you apply only for one and not the other one? Why do you specifically prefer that one and not the other one?
Well, one of the most important points not to go for Directive 2001/18/EC is that our applications are based on business plan. If we have commercial interest we would go for it, but if not, we are not going to authorise a crop, which has certain tolerance or resistance, which doesn't exists in Europe.

5. Why did you choose or didn't choose the "one door, one key principle"?
The triggers about the system are huge. If we apply for "one door, one key principle", we have to wait for the risk assessment of both of them. If one takes 4 years, the environmental risk assessment would take 10 years for example. the result can't be concluded until the assessment is not done. In this way the applicant should wait for 13 years, which is not profitable anymore. If you have a product supposed to be launched on the market within 5 years and it is launched with 10 years delay, the economic profit is lost during this procedure.

6. When did you apply for an authorisation and how long it took?
According to our own experience the approval procedure following Reg. (EC) No. 1829/2003 takes approximately 4 years and Dir 2001/18/EC takes up to 13 years.

7. When you were making the choice for the procedure what did you take into account?

8. Did you think about risk spreading?

9. How much were the monetary costs involved in your authorisation procedure?
Before we apply for an authorisation, we make a business plan and before the authorisation we have to prepare the biological material as seeds. This is lengthy procedure and involves research, time and costs in terms of millions of euros.

10. What was the impact of the "one door one key principle" for you as a company in terms of obtaining both types of the authorisation?
We don't use that often.

11. What are the advantages of this procedure for your company?
For our company there are no advantages.

12. What are the disadvantages of this procedure for your company?
The disadvantage is that it takes too long and in certain stage it is not useful. As it is now, we think that principle doesn't work as it is planned.

3.2 Interview with Bayer

1. What type of GMO product are you dealing with?
All crops in which Bayer CropScience offers technology: Cotton, Canola (Oilseed Rape), Soybean, Corn, Rice. Technologies include herbicide tolerance, insect resistance and hybrid traits.

2. What type of authorisation procedure did you follow Regulation(EC) No. 1829/2003 or Dir 18/2001?
We focus on import files to help facilitate global commodity trade, and because the cultivation of GMOs remains an unpredictable undertaking for technology providers, seed companies and farmers alike. Therefore in basically all cases we follow the procedure Regulation of 1829/2003.

3. What type of authorisation did you want to acquire (food/feed or environmental release)?
Authorization scope: Food and feed use, extended food scope (e.g. to cover GM pollen in honey or accidental presence of GM oilseed grains in mustard), import, processing, industrial use.

4. Why did you apply only for one and not the other one? Why do you specifically prefer that one and not the other one?
See above/business decision.

5. Why did you choose or didn't choose the "one door, one key principle"?
See above/ business decision.

6. When did you apply for an authorisation and how long it took?
On average, our import files take about 3.5 years until final approval. We expect these timelines to increase due to the fact that commercial products no longer carry single events only but are so-called stacks. Cultivation files can take up to 10 years or more (no Bayer example). We currently have a cultivation file for cotton in the system that was submitted in December 2012 and is in the risk assessment phase.

7. When you were making the choice for the procedure what did you take into account?
See above.

8. Did you think about risk spreading?
Not sure what this question is exactly aiming at? LLP, AP?
(Following our discussion on December 10, I understand you were referring to the use of the "one door, one key principle" and the potential scenario of a split scientific opinion for the food/feed scope on the one hand, and the cultivation scope on the other hand. As explained, we focus on import files and therefore in basically all cases follow the procedure Regulation of 1829/2003. In order to avoid the food/feed scope be held up in the system, respectively avoid the food/feed scope be blocked by a lengthy and unpredictable cultivation scope

application which could happen during the “one door, one key principle” , we usually keep application the scopes separate to ensure that food/feed can proceed.)

9. How much were the monetary costs involved in your authorisation procedure?

The cost of discovery, development and authorisation of a new plant biotechnology trait introduced between 2008-2012 is 136 million USD (approx. 100 million EUR).
see also
http://www.google.de/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=3&ved=0CEMQFjAC&url=http%3A%2F%2Fwww.croplife.org%2Fview_document.aspx%3FdocId%3D3338&ei=GPalUvHLMcPfswadxYCwBQ&usg=AFQjCNFZz9tiFvJPYAd56HrObkd9OIT8Vw

10. What was the impact of the “one door one key principle” for you as a company?

The new regulatory system required diligent follow-up when authorizations had to be renewed, and posed new challenges to products that were either not subject to renewal, or lost their commercial importance during the interim phase and therefore were no longer supported from the regulatory perspective and consequently withdrawn.

11. What are the advantages of this procedure for your company?

Possibility to compile one dossier to apply for all intended authorization scopes.

12. What are the disadvantages of this procedure for your company?

No disadvantages of the “one door one key principle” as such but shortcomings of the overall regulatory system in the EU that does not reflect biological and commercial realities incl. those of global trade.

Annex 4

Interview with EuropaBio

1. Do you have any statistics how many applications are sent for GMO Authorisation per year?

According to the database there are 9 submissions via Reg. 2003/1829 for the year of 2013. For the next year more than 10 renewal submissions are expected. It will be followed as 6 renewal submissions per year for previously authorised products.

2. How many applications are authorised per year (food/feed and deliberate release separately)?

Circa 5-6 food and feed imports per year, this takes approximately 49 months.

3. Do you think that there is a change since the Reg. (EC) No. 1829/2003 is in force? Could you explain it?

Before 2003 making the risk assessment process took longer. Nowadays, the EU Commission's decision takes too long than the risk assessment itself. The circumstances have also changed, therefore it is difficult to compare.

4. Under which legislation the applications are filed? (Reg. (EC) No. 1829/2003 or Di.r 2001/18/EC)

Mostly the applications are filed under Reg. (EC) No. 1829/2003.

5. Why the companies prefer the one you answered on the previous question and not the other legislation?

Companies are definitely applying for food and feed authorisation. Due to deadlock in the authorisation procedure GMOs are not getting authorised for cultivation and companies are more interested in imports.

6. Is "one door, one key principle" useful during the authorisation procedure, if yes-why?

The companies do use it. They all use Reg. (EC) No. 1829/2003 and if they want it. But it is not relevant now. Companies are not interested in cultivation, due to the deadlock as it has been previously mentioned.

7. Which guidelines are used for GMO authorisation?

EFSA's guidelines for applicants.

8. How long does it take for a company to get an authorisation for deliberate release and for Food and Feed uses (separately and together)?

Approximately, it takes 49 month for food/feed imports.
For cultivation authorisation, an example can be given with Maize in 1998, which took 38 months. Potato authorisation took 84 months, which is not since December 2013.

9. How do you see the current legislation for GMO authorisation?

For cultivation it doesn't work. For example with the Pioneer product the Commission failed to act in the end of 2013. The authorisation system for cultivation is not working. Feed and

food is working, but still very slow. Even if EFSA's opinion is published, it always exceeds the legal time to get an authorisation, thus the system works but not well.

10. Why do you think there are more than 60 GMOs for food and feed use authorised and only 2 for cultivation?

We need to authorise food/feed, if cultivation is not allowed. The lack of any type of authorisation leads to trade distractions. EU is forced to authorise, especially if EFSA has positive opinion.

11. What are the advantages of "one door, one key principle" for the companies?

One of them is that 1829/ more European Union level and in English

12. What are the disadvantages of "one door, one key principle" for the companies?

It cannot be said that there are really disadvantages.

13. How do you see the future plans of the Commission for GMO authorisation? Is there room for improvement?

We are a bit sceptical. They were implementing regulation 503/2013. It makes the EFSA's guidelines binding. Some political pressure was involved without scientific information. 90 days rat studies are introduced. According to Europa Bio there is no added value. Political involvement in the risk assessment is seen.

14. What do you think about the proposal of European Commission to grant Member States more subsidiarity on cultivation?

With this proposal it seems that cultivation in EU will be even more far away.

Annex 5

Interview with the European Commission

1. How many authorisations you have granted for GMOs per year?

2013	6
2012	8
2011	14
2010	14

2. What type of authorisation procedure they went through?

Almost all of the applicants submit applications under Regulation (EC) No. 1829/2003, which makes provision for authorisation for food and feed uses and cultivation and therefore they can apply for "one door, one key principle", but still most of them go only for food and feed authorisation.

3. Why do you think the companies went were following that type of procedure?

It seems to be more practical for them and easier in that they need only to prepare one file. However the possibility for a negative or positive outcome is the same regardless of the route chosen, because we as risk managers take our decisions based on the risk assessment of EFSA. If the applicant has submitted two applications, one for food and feed uses under Regulation (EC) No. 1829/2003 and a second for cultivation under Directive 2001/18/EC a negative answer for one application and positive for the other one is feasible. If only one application is submitted under Regulation (EC) No. 1829/2003 then if a negative EFSA opinion for part of the application were received authorisation would not be granted, because it would be considered as one application for which we could make one overall decision. From this perspective it seems that which procedure to follow is dependent on the scope of the application…

4. Do they use the "one door one key principle"?

Not very often.

5. How do you make the assessment? Based on scientific risk assessment only or there are also other factors? If so, do you give an advice to the applicants which procedure to follow?

We are risk managers and our decisions are based only on a scientific risk assessment from EFSA. There are no negotiations between us and the applicant. Sometimes the applicant has questions and therefore is contacting us, but we don't contact them if additional information is not needed.

6. How "one door one key principle" influences the EU market?

No answer

7. What are the advantages of this procedure?

Under Regulation (EC) No. 1829/2003 applicants can apply for both authorisations at the same time with one application. The costs are lower and the applicant can change the scope

of the application at any stage. Only one package of information is also seen as an advantage. Under Directive 2001/18/EC the applicant is free to choose a Member State for risk assessment, which gives wide range of flexibility to the applicants.

8. What are the disadvantages of this procedure?

The biggest disadvantage seems to be if applications for food and feed uses and cultivation are both made under Regulation (EC) No. 1829/2003 and the decision for part of the scope is negative. If the applicant files one application under Regulation (EC) No. 1829/2003, it means that the answer is valid for that application and not just part of the scope. Therefore if it is negative for one aspect, the overall outcome is negative. Therefore, if something doesn't go smoothly with one of the assessments, the other one is not going further either.

9. Do you have any negotiations with the applicant during the assessment (formal/informal)?

European Food Safety Authority is in charge of the risk assessment of GMO applications. After the scientific opinion is published, the procedure enters the risk management phase (EC and Member States authorities are the risk managers). We don't negotiate in terms of our decision. Only discussion seen as contact can be advice for labelling for example, but there is no discussion or negotiation related to the application as such.

Future plans:

On 13/07/2010, European Commission came with a proposal for amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory or part of it. The proposed amendment aims at providing a legal basis to the Member States to restrict or prohibit the cultivation of GMOs on their territory on grounds other than those based on the assessment of risks to health and the environment - risks which are currently being assessed at EU level.

This proposal may lead to more authorisations for cultivation at EU level and will leave some more room to the Member States to allow or restrict cultivation on their territory. In this respect, we think that the authorisation procedure will speed up and develop in a positive way.

Annex 6

Interview with the Researcher (Pim Lindhoudt)

1. What is your opinion for GMO's as a research with such a solid background in the field of Biotechnology?

In 70's, when I was still student I was concerned about GMO. I was part of plant protection organisations, which were against GMOs. The biggest concern was the uncertainty about the future consequences of GMO's in the nature... This opinion was based on scientific knowledge at that times and the risk wasn't clear yet. Over the years I have changed my opinion as my professional experience was developing. I have a clear opinion that genes can have horizontal gene transfer in the nature, therefore genetical modification happens naturally in the environment. Based on that I don't see the reason why we concern one gene transfer as a risk, while in the nature hundreds of gene transfers occur. Nowadays 20% of the world's area is planted with GMO's and we don't see a serious disaster related to that, so the perception of risk in different countries seems to be different.

2. Do you think that "one door, one key" principle is practical and applicable?

I don't have personal experience with that approval procedure, so I can't answer.

3. Do you know why only few GMO's are approved for environmental release and much more for feed/food use?

It seems that consumers' perception is playing biggest role, while making the decision. Consumers' organisations are influencing Commission's opinion, because in European Union citizen's opinion is as important as science.

4. Do you know what is the reason for the difference in the numbers of these 2 types approvals?

It is obvious that the Commission wants to limit the cultivation and if GMO's are part of our daily life, it is based on export, but not cultivated in EU. The society becomes more complex and influences the rules. People see the big companies trying to control the world and take over, so they European consumers don't want to allow that to happen. The biggest emotion is about the big companies trying to squeeze you and tell the rules. Emotions are so tremendous, that people don't listen each other. It turns out that food is also about emotions and tradition.

5. Do you consider the "one door, one key" principle as an advantage or disadvantage?

I don't have a personal experience with the procedure itself, but the only thing I can say is that, I am also surprised that we have the approval procedure but it doesn't work.

6. Do you think that it is fair for the companies to follow these difficult procedure and getting an authorisation is like "mission impossible"?

No it is not fear, it is discrepancy! As I said before, the fear from the big companies is huge and food is seen as emotion. I see that rules are dictated by minority, because most of the people don't express their opinion, but those who have strong negative opinion express it loudly. In the end it seems as then opinion of all the citizens.

7. What do you think is the economic impact of this procedure to the companies?
Violating open competition, because they are limited and the choice on the market is missing. The more choices you have, better business opportunities appear.